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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,655	03/14/2005	Edwin Odell Miner	0M02-01	2401

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,655	MINER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Information Disclosure Statement (IDS) filed 01/03/06 is acknowledged.

Claims 1-20 are pending in this action. Claims 1-20 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 12 recite the limitation "*a.k.a. propylene glycol*". The claims are indefinite because it is unclear whether the limitation is merely exemplary in nature or whether it is actually intended to be part of the claim. It is suggested that the limitation "a.k.a. propylene glycol" be either deleted or positively recited.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Leuven (U.S. Pat. No. 4,184,974) in view of Dodd *et al.* (U.S. Pat. No. 6,344,218).

The instant invention is drawn to a liquid antiseptic comprising: water; silver ion; polypectate and ethylenediaminetetraacetic acid (EDTA). The instant invention is also drawn to a method of preparing a liquid antiseptic, comprising the steps of: combining water, silver ion

and aqueous ammonia to form a silver ammonium complex solution; combining ethylenediaminetetraacetic acid (EDTA), sodium polypectate, glycerine and water to form a chelating solution; and combining the silver ammonium complex solution with the chelating solution to form a chelated silver solution.

Van Leuven ('974) teaches a liquid biocidal and cleanser composition comprising lauryl diethanolamide (2.7-6.5% by wt.), propylene glycol (1.2-2.5% by wt.), glycerine (4-6% by wt.), sodium polypectate (100-400 parts/million (ppm)), silver ion (13-250 ppm), a detergent that is nondeleteriously reactive with sodium polypectate (3.6-8.5% by wt.) and a sufficient water soluble base such as ammonium hydroxide to maintain a pH in the range from about 7.2 to 8.8; the balance of the composition being primarily sterile distilled water (see reference column 2, lines 1-19) and Abstract.

The silver ion can be added to the composition as silver nitrate (col. 2, line 20). The detergent can be the reaction product of from about 2.5 to about 6% by wt. dodecyl benzene sulfonic acid or a water-soluble salt thereof and from about 1.1% to about 3% by wt. triethanolamine (col. 2, lines 21-24).

Van Leuven teaches that the composition can be used for a variety of purposes such as a cleaner, topical biocide agent or vaginal lubricant (col. 2, lines 1-6). The composition is also useful for preserving human corpses, for treating condyloma and Herpes virus, for preventing Staphylococcus infection and as a lubricant for the delivery of a child at birth (col. 2, lines 25-29).

According to Van Leuven, the invention overcomes the undersirable effects of silver compounds by forming a silver polypectate that is completely stable at the specified concentrations (col. 2, lines 32-44).

In addition to the silver ion, which is preferably added as silver nitrate in this composition, there is sodium polypectate, which has a strong chelating activity with the silver (col. 2, lines 45-62). Van Leuven teaches that the proportion of sodium polypectate in the composition is in the range of about 100 to about 400 ppm by wt. The lower concentration of 100 ppm by wt. of sodium polypectate is found sufficient to provide adequate chelating activity with the silver ion to maintain it as a stable composition and inhibit its oxidation or decomposition upon exposure to light. It is believed that the sodium polypectate serves to ionize the silver in the composition to yield silver ion, which has biocidal activity (col. 3, line 60 – col. 4, line 12).

The composition also contains from about 3.6 to about 8.5% by wt. of a water-soluble detergent that is nondeleteriously reactive with sodium polypectate. This range meets Applicant's claimed range of surfactant of about 4.0-8.75%. Suitable examples of such a detergent is a linear alkyl sulphonate having from about 10 to about 12 carbon atoms in the alkyl chain. Such a sulphonate can be provided in the biocidal composition by using dodecyl benzene sulfonic acid or a water-soluble salt thereof in the range of from about 2.5 to about 6% by wt. of the composition and triethanolamine, in the range of from about 1.1% to about 3& by wt. of the composition (col. 4, lines 45-61). Commercially available dodecyl benzene sulfonic acid or its water-soluble salt can have minor variations in chain length and a few isomers of the dodecyl chain may also be present. Such material is widely used as surface-active agents common in

detergent compositions. These materials offer good cleaning action, lubricity and appropriate viscosity without adverse effects (col. 4, line 63 – col. 5, line 2). For higher viscosity and cleansing action, detergent materials such as sodium lauryl sulfate can also be used (col. 5, lines 14-44).

The composition also includes propylene glycol in the range of from about 1.2 to 2.5%. This material also has some bacteriocidal activity which cooperates with that of the silver to enhance the biocidal activity of the composition (col. 5, lines 45-55).

The composition also includes glycerine in the range of from about 4 to 8% (col. 5, lines 56-57) and about 4 to about 10% (see claim 1). This range meets Applicant's claimed glycerine range of about 5.5-11.5%.

The liquid biocidal composition also includes a small amount of pH adjuster such as a water-soluble base to maintain the pH in the range of from about 7.2 to 7.8 (col. 6, lines 6-8). This range is important for maintaining the stability of the composition over a prolonged period of time, for effective biocidal action and is also preferred for repeated application of the composition to the skin. Ammonium hydroxide is found to be quite compatible for use with the combination of sodium polypectate and silver nitrate (col. 6, lines 9-22).

The Examples at columns 6-14 demonstrate methods for the preparation of various compositions, such as cleansing agents. Example 1, for instance, shows the preparation of a topical cleansing agent according to the invention. A solution "A" comprising a silver ammonium complex was prepared by combining silver nitrate, distilled water and concentrated aqueous ammonia. The components were mixed together. A solution "B" was prepared by mixing glycerine, sodium polypectate and fresh distilled water. A solution "C" was prepared by

dissolving FDA #1 and #5 in distilled water. The topical cleansing agent was then prepared in a silver-lined reactor, to which distilled water and aqueous ammonia were added, to bring the water to a pH of at least 7.2. Carsofoam (containing triethanolamine, dodecylbennzene sulfuric acid, propylene glycol, lauryl diethanolamide and soft water) was then mixed into the contents of the reactor and stirred. The topical cleansing agent was packaged to avoid degradation of the silver due to sunlight.

With regards to the ranges claimed by Applicant, such as the ranges/amounts of 1,2-propanediol, sodium polypectate, water and silver ion, Van Leuven does not explicitly teach the precise ranges, but does appear to teach similar and/or overlapping amounts of each component. Moreover, no unexpected results have been observed, which accrue from the instantly claimed ranges and/or amounts, since the prior art vividly teaches a liquid biocidal cleansing composition comprising the same components, employed in effective amounts to yield a suitable biocidal composition. It would have been deemed obvious to one of ordinary skill in the art to determine suitable/effective ranges and/or amounts through routine or manipulative experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art. Furthermore, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, the prior art expressly teaches a liquid biocidal composition comprising

suitable amounts of each particular component (i.e., water, polypectate, silver ion, glycerine, surfactant & propylene glycol) to result in a stabilized and effective cleansing composition.

Van Leuven teaches chelation activity between sodium polypectate and silver ion to maintain stability and inhibit oxidation or decomposition of the composition (col. 3, line 60 – col. 4, line 35). Van Leuven does not teach ethylenediaminetetraacetic acid (EDTA).

Dodd *et al.* ('218) teach stable aqueous skin deodorizing and sanitizing compositions that comprise chelators, such as ethylenediaminetetraacetic acid (EDTA) and other aminocarboxylate chelators, salts and mixtures thereof (see col. 20, lines 1-18). Dodd *et al.* teach that chelators, such as EDTA can increase preservative effectiveness against Gram-negative bacteria, especially Pseudomonas species (col. 20, lines 12-18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the chelating agent, EDTA, as taught by Dodd *et al.* within the liquid biocidal compositions of Van Leuven. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Dodd *et al.* teach stable skin deodorizing and sanitizing compositions that comprise chelators such as EDTA and explicitly teach that EDTA is an effective chelating agent useful for its' preservative properties, especially against Gram-negative bacteria. The expected result would be a stabilized, highly effective liquid antiseptic formulation that exhibits enhanced biocidal properties and effects.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HUMERA N SHEIKH
PRIMARY EXAMINER

Art Unit 1615

March 30, 2007

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